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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/848,774	05/03/2001	Igor Gonda	AERX058CON3	8982

24353 7590 04/15/2003

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EXAMINER
LEWIS, AARON J

ART UNIT	PAPER NUMBER
3761	8

DATE MAILED: 04/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/848,774	GONDA ET AL.	
	Examiner	Art Unit	
	AARON J. LEWIS	3761	

-- The MAILING DATE of this communication appears on the cov r sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 December 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 22-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schenk et al.(WO 90/07351) in view of Velasquez et al.('548).

As to claim 22, Schenk et al. disclose a method of treating a patient comprising the steps of: supplying a predetermined amount of dry powder (11) to an inhalation device; releasing a pressurized gas (figs.1-6) over a predetermined amount of dry powder to create an aerosolized suspension (16) comprising powder suspended in air; and inhaling the aerosolized suspension at a flow rate and volume sufficient to allow the patient to absorb in the bloodstream a controlled dose of medicament.

The differences between Schenk et al. and claim 22 are insulin as the dry powder medicament and the recited intended result of the insulin containing 2-10 times higher the amount needed to be absorbed in the blood stream of a patient and the intended result of 1-50 units of insulin being absorbed into a patient's bloodstream.

Velasquez et al. teach a variety of dry powder medicaments as inhalable powders including insulin as a dry powder medicament for inhalation by a patient.

It would have been obvious to modify the dry powder in Schenk et al. to employ dry powder insulin as the medicament because it would have provided an easy and painless manner of delivering insulin to patients as taught by Velasquez et al..

As to the recited intended result of the amount of insulin employed and the amount of insulin being absorbed, it is submitted that the amount of insulin employed and the amount absorbed can be arrived at through mere routine obvious experimentation and observation. That is, the amount of insulin stored in the inhalation device and the amount being absorbed would vary in dependence upon the age, sex and severity of the diabetes of the patient being treated. Consequently, one of ordinary skill would realize that the amount stored and absorbed would need to be tailored to the particular patient's medical needs.

As to claim 23, inasmuch as Schenk et al. as modified by Velasquez et al. teach a method and device for treating diabetes, is stands to reason that the administration protocol would have included repeated inhalation (administration) of insulin to maintain an adequate concentration of medicament in a patient's bloodstream.

As to claim 24, Schenk et al. as modified by Velasquez et al. as discussed above with respect to claim 22 also discloses the inhalation in a single breath (page 10, lines 1-30) the aerosolized suspension adequate to allow absorption of a controlled amount of insulin into a patient's blood stream.

As to claim 25, Schenk et al. as modified by Velasquez et al. as discussed above also teach flowing at least a portion of the aerosolized suspension through a mouthpiece (20) on the device and into the patient's lungs in a manner sufficient to cause the patient to absorb a controlled quantity of insulin.

As to claim 26, inasmuch as Schenk et al. as modified by Velasquez et al. teach a method and device for treating diabetes, is stands to reason that the administration

protocol would have included repeated inhalation (administration) of insulin to maintain an adequate concentration of medicament in a patient's bloodstream.

As to claim 27, Schenk et al. as modified by Velasquez et al. as discussed above also teach mechanically delivering a predetermined amount of dry insulin powder (figs.1-6 of Schenk et al.); aerosolizing the dry powder to form a dust cloud (e.g. fig.1); inhaling a single breath (page 10, lines 24-28).

As to claim 28, inasmuch as Schenk et al. as modified by Velasquez et al. teach a method and device for treating diabetes, is stands to reason that the administration protocol would have included repeated inhalation (administration) of insulin to maintain an adequate concentration of medicament in a patient's bloodstream.

Claims 29-38 are substantially equivalent in scope to claims 22-28 and are included in Schenk et al. as modified by Velasquez et al. for the reasons set forth above with respect to claims 27-28.

As to the recited claimed limitations defining a controlled quantity of insulin which is sufficient to achieve the desired result, Schenk et al. (page 3, lines 5-3; page 4, line 27-37) disclose a device which maximizes the amount of aerosolized powder medicament thereby facilitating maximum amounts of medicament inhaled and absorbed into a patient's bloodstream. That is, given that Schenk et al. disclose aerosolizing most of the medicament within the aerosolization chamber (16), the amount of medicament available for inhalation by a patient is predictable.

As to claims 37 and 38, the rate and volume of in Schenk et al. (figs.1-6) includes mechanical means (springs 27,32) for providing fixed rates and volumes as well as

means for varying the rate and volume by varying the spring constants and varying the pressure being applied to pump (42).

Response to Arguments

3. Applicant's arguments with respect to claims 22-38 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

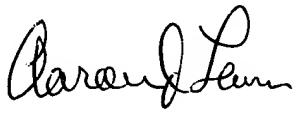
4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON J. LEWIS whose telephone number is (703) 308-0716. The examiner can normally be reached on 9:30AM-6:00PM M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, WEILUN LO can be reached on (703) 308-1957. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



AARON J. LEWIS
Primary Examiner
Art Unit 3761

Aaron J. Lewis
April 7, 2003